REMARKS

This invention provides for a transdermal therapy system (TTS) which comprises an active agent depot and a matrix wherein at least either the active agent depot or the matrix comprises a support material which consists of paper. This invention further provides for a process for preparing the inventive TTS. The inventive TTS exhibits improved processing and delivery properties (see Example I and Example 2).

It is believed that no fee is required for the consideration of this Amendment. If it is determined that a fee is due, the Assistant Commissioner is authorized to charge such fee, or credit any overpayment to Deposit Account 50-0320.

Entry of this Amendment is requested since it does not add any material that requires further consideration and/or search and either places the application in better condition for allowance or in better form for appeal. By the entry of this Amendment, the claims will be very similar to those allowed by the Europe Patent Office (see attached sheet).

Support for the active agent recited in claim 7 is found on page 4, lines 26 to 31. Thus, no new matter is added.

Claims 7 to 14 stand rejected under 35 USC §103(a) as being unpatentable over Hoffman, U.S. Patent 5,820,876 in view of Nichols U.S. Patent 4,804,541. Applicants respectfully disagree as Hoffman taken with Nichols in any fair combination do not suggest a TTS which comprises an active agent depot or a matrix that comprises a support material which consists of paper. Accordingly, it is urged that the rejection does not establish a *prima facie* case of obviousness and reconsideration and withdrawal of the rejection are requested.

The rejection acknowledges that Hoffman does not disclose a TTS wherein the active agent depot or the matrix comprises a support material consisting of paper. Office Action at 3.

In order to correct the deficiency, the rejection relies upon Nichols alleging that this patent teaches

> a TTS with a backing material impermeable to the active agents. The TTS further comprises a pressure sensitive adhesive component that affixes to the skin and a matrix component that contains the active agents. The matrix material is can be made of absorbent paper.

Office Action at 3. In responding to Applicant's arguments, the rejection advances the argument:

> the matrix material is recited to be cellulose based, which can be fibrous. Paper is not mentioned, as a matrix material, yet the suggestion of cellulose based fibrous material is there. This reference does not need to encompass each and every element of the claimed invention since it is applied under §103 and need only suggest the elements to obviate the claimed invention. Nichols discloses a TTS where the carrier material is listed as absorbent paper, along with similar other carrier material as listed in Hoffman. Nichols also delivers estradiol, a sexual hormone. Nichols provides the appropriate support material to Hoffman's structure. It is not necessary for Nichols to contain a drug depot, since it is merely a supportive reference showing the level of skill in the art to use paper material as carrier components in TTS. It would have been obvious to a skilled artisan to combine the teachings since both transdermal devices delivered sexual hormones, and comprises similar structural components (i.e. impervious backing layer, medicament layer, etc.).

Office Action at 4-5. Applicants respectfully disagree since Nichols does not suggest using paper or any cellulose-based derivative as a support material in an active agent depot, matrix or both. Nichols merely suggests that what the rejection terms "cellulose-based fibrous materials" may be included in a TTS for their absorbent properties; a property that, implies that the material is not structurally rigid.

This present invention provides for, *inter alia*, a TTS in which the active agent depot or the matrix comprises paper as a support material. As discussed on pages 1 to 3, the prior art does

not teach using paper for this purpose and the prior materials used as support material are fundamentally different from paper (see especially page 2, line 19 *et seq.*). Moreover, the use of paper as a support material for these components has distinct advantages over the prior material, such as fabrics. Examples 1 and 2 demonstrate some of these advantages.

Hoffman provides for a conventional TTS. As discussed on page 2, line 25 *et seq.*, the depot and the matrix components do not contain paper. The support materials disclosed in Hoffman, which distribute the active substance within the fabric, are a planar fabrics such as a nonwoven fabric such as cotton (see col. 3, lines 10 to 19; col. 7, line 18 to 20). Thus, not only is Hoffman "silent" with respect to the inclusion of paper for these components, the patent teaches away from the use of paper since paper has properties which are different from fabrics (see page 2, third paragraph of the specification).

Nichols does not correct this deficiency. The entire disclosure of Nichols is directed to absorbent materials. In column 2, lines 56 to 58, Nichols states

> The benzyl alcohol solution can also be maintained in place by imbibing or absorbing it in a suitable solid carrier such as an absorbent pad of fibrous material or a porous benzyl-alcohol-insoluble polymeric matrix, the latter being preferred. It is particularly advantageous to incorporate the medicament solution in a gelled cellulose triacetate matrix, as described for example in Nichols U.S. Pat. No. 3,846,404 incorporated herein by reference.

(Emphasis added). In column 3, lines 2 to 11, Nichols indicates suitable carriers may be

> absorbent paper, fibrous batts such as cotton batting and various porous or microporous polypermeric gel compositions such as partially cross-linked polyvinyl alcohol, polyvinyl pyrrolidone or polyacrylamide; and porous or microporous gels of cellulose esters or ethers including cellulose acetate, cellulose butyrate, cellulose nitrate and the like. Particularly preferred is microporous cellulose triacetate gel as pointed out above.

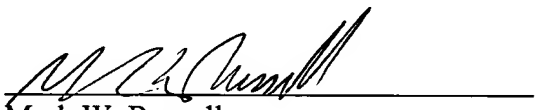
The common feature of the cellulose-based derivative is that they are absorbent. Further, one skilled in the art would not expect that materials such as fibrous batts or cotton fibers would add structural rigidity to a TTS since these materials are flimsy.

In view of the foregoing it is respectfully urged that Nichols does not suggest using paper in a TTS as a support material since there is nothing in Nichols that indicates that paper may be used for these purposes. In Nichols, all the cellulose materials mentioned are known to exhibit good absorbent properties, but not for being very rigid. Hence, Applicants cannot agree with the conclusion in the rejection that Nichols corrects deficiencies found in Hoffman and suggests using paper as a support material, an element recited in the present claims.

Thus, in view of the foregoing, reconsideration and withdrawal of this rejection is requested and favorable action is earnestly solicited.

Respectfully submitted,

FROMMER LAWRENCE & HAUG LLP
Attorneys for Applicant

By: 

Mark W. Russell
Reg. No. 37,514
Tel. (212) 588-0800

EPA/EPO/OEB
D-80298 München
+49 89 2399-0
TX 523 656 epmu d
FAX +49 89 2399-4465

Europäisches Patentamt	European Patent Office	Offic européen des brevets
Generaldirektion 2	Directorate General 2	Direction Générale 2

Schmidt, Werner, Dr.
LTS LOHMANN Therapie-Systeme AG,
Lohmannstrasse 2
56626 Andernach
ALLEMAGNE

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Anmelder: LTS Lohmann Therapie-Systeme AG		

Mitteilung gemäß Regel 51(4) EPÜ

Hiermit wird Ihnen mitgeteilt, daß die Prüfungsabteilung beabsichtigt, ein europäisches Patent auf der Grundlage der obengenannten europäischen Patentanmeldung in der sich aus folgenden Unterlagen ergebenden Fassung zu erteilen:

In der Fassung für die Vertragsstaaten:
AT BE CH LI CY DE DK ES FI FR GB GR IE IT LU MC NL PT SE

Beschreibung, Seiten:

1-7 veröffentlichte Fassung

Patentansprüche, Nr.:

1-6 eingegangen am 11.09.2001 mit Schreiben vom 10.09.2001

Zeichnungen, Blätter:

1/2,2/2 veröffentlichte Fassung

Mit folgenden Änderungen der obengenannten Unterlagen durch die Abteilung:

Anspruch, Nr.: 1*

Bemerkungen:

* Art.84 EPÜ und Richtlinien C-III 4.6

In der Anlage erhalten Sie eine Kopie der obengenannten Unterlagen.

Die Bezeichnung der Erfindung in den drei Amtsprachen des Europäischen Patentamtes, die

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Claims

1. A transdermal therapeutic system containing as essential features
   a) a backing layer (10) remote from the skin and impermeable for the active substance,
   b) at least one active substance depot (14),
   c) a matrix containing the active substance depot and controlling the delivery of the active substance (12), and
   d) a pressure-sensitive adhesive fixing device (16) for the therapeutic system on the skin (18), the depot or the matrix or both containing support materials, wherein the support material consists of paper and the acive substance is lidocaine, diphenylhydramine hydrochloride, salbutamol, 5-fluorouracil, one or more sexual hormones, a gestagen, or fentanyl.

2. The transdermal therapeutic system as claimed in claim 1, wherein the active substance is estradiol, norethindrone acetate or levonorgestrel.

3. The transdermal therapeutic system as claimed in claim 1 or 2, wherein the paper has a basis weight of from 9 to 60, preferably from 15 to 40 and particularly from 20 to 35 g/m².

4. A process for the improved production of a transdermal therapeutic system with a deviation of the amount of active substance applied of less than 2%, wherein the active substance is applied in conventional manner by means of a tampon to a support material which consists of paper.

5. The process as claimed in claim 4, wherein the deviation of the amount of active substance applied is less than 1.2%.

6. The process as claimed in claim 4 or 5, wherein the paper has a basis weight of from 9 to 60, preferably from 15 to 40 and particularly from 20 to 35 g/m^2.